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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,384	04/01/2004	Eilaz Babaev	103514-0011-103	7585
Matthew P. Vincent, Esq. Ropes & Gray LLP One International Place Boston, MA 02110-2624			EXAMINER CHENG, JACQUELINE	
			ART UNIT 3768	PAPER NUMBER
			MAIL DATE 09/17/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/815,384

**Applicant(s)**

BABAEV, EILAZ

**Examiner**

JACQUELINE CHENG

**Art Unit**

3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 8-17, 37-49 and 63-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-17, 37-49 and 63-81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/08)  
Paper No(s)/Mail Date 1/28/08, 4/25/08
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments filed February 8, 2008, with respect to the rejections of the claims have been fully considered, however upon further consideration, new grounds of rejection are made as discussed below.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. **Claims 1-5, 8-12, 14-17, 37-42, 47-49, 63-77, and 80-81** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kost (US 6,041,253) in view of Gerasimenk (SU 1106485 A) further in view of Duarte. Kost discloses an ultrasonic method wherein application of ultrasound is used to facilitate transport of a compound, such as a drug, through the skin (col. 4 line 45-51). The drug can be in the form of a gel, ointment, lotion, insulin, or antibiotics, which are all used in order to help heal the patient, having a therapeutic effect (col. 10 line 41-49). The probe tip of the ultrasonic energy being applied from a non-contact distance from the tissue, such as 3 cm away (col. 13 line 26-33). Kost discloses that in a preferred embodiment the drug is applied to the site and then the ultrasound is applied immediately thereafter. Kost also discloses that other enhancers can be applied during the ultrasound application, but does not explicitly disclose how

the other enhancer is to be applied simultaneously with the ultrasonic waves (col. 11 line 13-16).

It would be obvious to one skilled in the art at the time of the invention to use any well known method of applying enhancers with an ultrasonic wave such as the method disclosed by Gerasimenk. Gerasimenk discloses a method of sonophoresis wherein the medicinal solution (which is capable of containing an enhancer such as disclosed by Kost, col. 4 line 43-51) and the ultrasonic waves are applied simultaneously by spraying the solution in the form of an aerosol towards the wound from a non-contact distance to the tissue (abstract). The aerosol plume created from a liquid which is passed through the acoustic unit to the end of the acoustic unit where the aerosol plume is detached from this end of the acoustic unit (distal radiation surface) (col. 2 paragraph 1).

4. As to the ultrasonic energy having an intensity to provide a therapeutic effect to the tissue, Gerasimenk discloses that the method disclosed is for therapeutic methods for treatment of wounds and that the ultrasonic wave is applied at a frequency of 20-100 kHz (abstract). This range is well known in the art to be effective in wound healing by stimulating regeneration of cells, such as disclosed in Duarte (col. 1 line 66-col. 2 line 4, col. 4 line 62-65). Kost also discloses generating ultrasonic waves in this range (of 20-40 kHz, col. 4 line 59-62), so therefore in view of the information provided in Duarte, both prior arts teach delivering ultrasonic energy with an intensity of penetrating the tissue to provide a therapeutic effect to the tissue of wound healing.

5. **Claims 43-46** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kost in view of Gerasimenk in view of Duarte as applied to claim 37 above, and further in view of

Martin (US 6,500,133). Martin discloses a medical instrument that uses ultrasonic energy for various medical applications. It is obvious that in order to apply Kost or Gerasimenk and provide ultrasonic therapeutic energy to a wound, the energy must have a particular amplitude, frequency, radiation surface area and perimeter that is capable of achieving the therapeutic effect. These surface and perimeters can be of various shapes and sizes as the abstract and col. 3 line 8-10 of Martin discloses. Martin also specifically discloses using concave as well as convex geometry (col. 3 line 19-35) as shapes for the radiation surface.

6. **Claim 1-4, 9-17, 63, 66, 68, 70, 71, 73, 75, 77, 79, and 81** are rejected under 35 U.S.C. 103(a) as being unpatentable over Henley (US 6,458,109 B1) in view of Manna (US 5,516,043 A) in view of Duarte (US 6,273,864 B1). Henley discloses a wound treatment apparatus comprising a bandage which provides a seal around a perimeter of the wound and creates a cavity over the wound (from a non-contact distance). The bandage system also comprises a nebulizer (abstract), which can be any well known nebulizer in the art (col. 5 line 57-58) such as one disclosed by Manna which uses ultrasound energy in the frequencies of between 15-100 kHz (col. 6 line 27-34) which is well known in the art to be effective in wound healing by stimulating regeneration of cells, such as disclosed in Duarte (col. 1 line 66-col. 2 line 4, col. 4 line 62-65), and medication delivery system. The medication delivery system provides for delivery of both liquid medication (applying medicament to tissue) or aerosol by means of the nebulizer (delivering ultrasonic energy simultaneously with liquid spray) to the wound (col. 5 line 63-65). Since Henley does not explicitly disclose an order to which the liquid medication and the spray be applied it would be obvious to apply them in any order.

*Conclusion*

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE CHENG whose telephone number is (571)272-5596. The examiner can normally be reached on M-F 10:00-6:30.
8. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian L Casler/  
Supervisory Patent Examiner, Art Unit  
3737

JC